

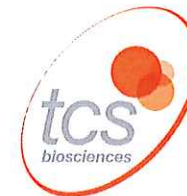
STATEMENT

We, TCS Biosciences Ltd., having a registered office at Botolph Claydon, Buckingham, MK 18 2LR, England assign Sanmedico SRL having a registered office at str. A. Corobceanu 7A, apt. 9, Chişinău MD-2012, Moldova, as Authorized Representative in correspondence with the conditions of directive 98/79/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Date : 21 August 2018

Signature: Sue Brown



SELF DECLARATION OF CONFORMITY

We declare under our sole responsibility in accordance with MHRA account number 0000009546 that the following CE marked products:

GMDN Term	GMDN Code	TCS product code and description
General microbial isolate identification control IVD	63319	Selectrol – All MM codes

conform to the relevant provisions of the In-vitro Diagnostic Medical Devices Directive 98/79/EC and The Medical Devices Regulations 2002 (SI 2002 No.618) and The Medical Devices (Amendment) Regulations 2003 (SI 2003 No.1697) for in-vitro diagnostic medical devices.

This declaration is made on the basis of meeting the requirements of Annexes I and III of the In-Vitro Diagnostic Medical Devices Directive 98/79/EC and continued maintenance of an approved Quality Management System meeting the requirements of ISO 9001, as certified by BSI, certificate number FS 28907.

Signed by: Sue Brown

Date: September 2020

Name: Sue Brown
Position: Quality Assurance & Regulatory Affairs Manager

Signed by: Lynda Preston

Date: September 2020

Name: Lynda Preston
Position: Managing Director

Manufacturer
TCS Biosciences Ltd
Botolph Claydon
Buckingham MK18 2LR
UK

EC Authorised Representative
TCS Biosciences Europe B.V.
Provincialeweg 6
9864 PD Kornhorn
The Netherlands

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

TCS Biosciences Limited
Botolph Claydon
Buckingham
MK18 2LR
United Kingdom

Holds Certificate Number:

FS 28907

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

The procurement, manufacture, design, development and sale of a range of diagnostic products for clinical, pharmaceutical, food and environmental laboratory testing.

For and on behalf of BSI:



Matt Page, Managing Director Assurance - UK & Ireland

Original Registration Date: 1994-08-11

Latest Revision Date: 2022-01-14

Effective Date: 2022-01-27

Expiry Date: 2025-01-26

Page: 1 of 1



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Certificate of Registration

ENVIRONMENTAL MANAGEMENT SYSTEM - ISO 14001:2015

This is to certify that:

TCS Biosciences Ltd
Botolph Claydon
Buckingham
MK18 2LR
United Kingdom

Holds Certificate Number:

EMS 590359

and operates an Environmental Management System which complies with the requirements of ISO 14001:2015 for the following scope:

The procurement, manufacture, design, development and sale of a range of diagnostic products for clinical, pharmaceutical, food and environmental laboratory testing.



For and on behalf of BSI:

Matt Page, Managing Director Assurance - UK & Ireland

Original Registration Date: 2013-06-10

Latest Revision Date: 2022-01-14

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SELECTROL

Discurile cu tulpini de referință Selectrol® sunt destinate utilizării în laboratoarele de microbiologie în scop de control a metodelor de testare. Fiind **derivați de primă generație** trasabili la tulpinile de tip național renumite, discurile Selectrol sunt bine primite în laboratoare acreditate pentru producția culturilor de lucru.

Discurile Selectrol sunt un produs microbial congelat fabricat exclusiv din culturi ale NCTC (Colecția Națională a Tipurilor de Culturi) și NCPF (Colecția Națională a Fungilor Patogeni). Viabilitatea microorganismelor este stabilizată prin incorporarea cărbunelui activat în disc și a silica gelului din flacon.

PRECAUȚIUNI ȘI PĂSTRARE

- Discurile Selectrol conțin microorganisme patogene și trebuie folosite doar în laboratoarele special echipate pentru manipularea acestora de către microbiologi calificați.
- Păstrați la temperatura indicată pe flacon. Pierdere de viabilitate poate apărea la păstrarea necorespunzătoare pe timp îndelungat (temperaturi mai mari decât cea indicată pe flacon).
- Lăsați flaconul să ajungă la temperatura camerei și închideți flaconul imediat după îndepărtarea duscului/discurilor. Umiditatea din aer ar putea duce la reducerea numărului de microorganisme de pe disc.
- Nu folosiți produsul după expirarea termenului de valabilitate sau dacă culoarea silica gelului din flacon își schimbă culoarea. Aceștia sunt indicatori ai pierderii viabilității și modificărilor în antibiotice și reacții chimice.

Îndepărtarea unui disc din flacon: aceasta se efectuează ușor cu forceps steril sau ansă sterilă de 10 µl.

Utilizarea cu medii solide: Plasați discul pe mediul solid corespunzător. Lăsați discul să se înmoaie timp de 10-15 minute. Placa poate fi plasată în incubator pentru a grăbi procesul. Apoi împrăștiati discul pe suprafața mediului și incubați la condițiile optime/corespunzătoare.

Utilizarea cu medii lichide: Plasați discul în 1-10ml de bulion corespunzător. Amestecați ușor bulionul pentru a dilua discul, evitând formarea aerosolilor. Incubați la condițiile optime/corespunzătoare. Pentru uz rapid, folosiți metode alternative precum dizolvarea discului și incubarea bulionului la 35-37°C timp de o oră apoi să-l folosiți imediat. Puteți face careva experiențe proprii pentru a descoperi metoda de diluție corespunzătoare Dvs.

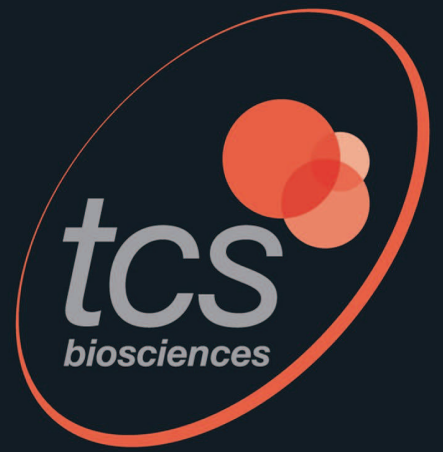
Limitări: Sub-cultura repetată poate cauza modificare a caracteristicilor tulpinii. Este recomandată folosirea discurilor proaspete pentru fiecare set de testări.

În laboratoarele de acreditare, discurilor pot fi folosite doar pentru producerea stocurilor de lucru. Sub-cultura de apoi va invalida uzul lor.

RUPERE, SCURGERI ȘI ELIMINARE

1. Toate discurile expuse, pachetele contaminate și sticlele stricate trebuie plasate într-un container corespunzător și incinerate sau autoclavate la 121°C timp de 30 minute.
2. Flacoanele întregi pot fi îndepărtate cu forceps, spălate cu soluție bactericidă corespunzătoare, uscate și utilizate ulterior.
3. Toate suprafețele contaminate trebuie dezinfectate cu soluție bactericidă corespunzătoare.

accuracy and quality as a science

The background of the lower half of the image is a close-up photograph of several petri dishes containing a red agar medium. A metal pipette tip is visible in the center, dispensing a small amount of the red liquid into one of the dishes. The focus is sharp on the dish in the foreground, with others blurred in the background.

Selectrol®
Technical
Guide



Selectrol® : Manufactured under licence from Public Health England Culture Collections

SELECTROL® - FREEZE-DRIED ORGANISMS IN A DISC

Quality control of microbial characterisation tests, culture media and antimicrobial susceptibility determinations is best accomplished by the use of microorganisms with well-documented and stable phenotypic and genotypic characteristics.

Bacterial and fungal strains have been selected and recommended by expert bodies, such as **EUCAST**, **CLSI** and the European Pharmacopoeia, on the basis of their suitability for monitoring test performance and ensuring the validity of results for testing used in clinical, food, pharmaceutical, water and veterinary laboratories.

Products derived from the cultures in the collections should be manufactured using the minimum number of sub-cultures, to minimise the possibility of alterations to the phenotype due to mutations. See also page 14.

Selectrol strains are manufactured exclusively from Public Health England Culture Collections (NCTC® and NCPF®) and are first generation subcultures, unlike many products on the market which are 2nd, 3rd or 4th generation subcultures. They are preserved by long-term storage as freeze-dried cells in order to minimise any alterations to the phenotype caused by mutations.

Passages

A Selectrol® disc is a first generation subculture from a **master culture** sourced from Public Health England Culture Collections, and is designed to be used to obtain **working stock** cultures for use in testing. It is generally accepted that no more than a total of five passages should be made from the **master culture**, in order to avoid genetic drift and mutant selection. Therefore, no more than four passages (fresh cultures) from the **working stock** should be made.

Shelf life

For most strains, Selectrol® discs are guaranteed to contain at least 10⁶ organisms at the time of purchase; this number is sufficient to ensure that when the discs are used and stored as directed there will be viable organisms cultivable up to the stated end of the shelf life, which is usually 9 months from the time the vial is first opened.

Quality Control

Selectrol® batches are tested in our UKAS accredited testing laboratory number 2496. A test report for each batch of Selectrol® can be accessed via our website. The reporting of Selectrol® test results via the website comes under our UKAS accreditation.

Selectrol® cultures are rigorously tested to confirm identity, to confirm the possession of essential phenotypic characteristics and to exclude contamination with other organisms. Photographic evidence of the test results is retained for each batch, along with retained appropriately stored samples.



Glossary

AMRHAI: Antimicrobial Resistance and Healthcare Associated Infections reference unit

ATCC®: American Type Culture Collection. ATCC® strains are listed for reference only. ATCC® is a registered trademark of the American Type Culture Collection.

BSAC: British Society for Antimicrobial Chemotherapy - Now superseded by EUCAST

CLSI: Clinical Laboratory Standards Institute. (USA)

CPE: Carbapenemase Producing Enterobacteriaceae

CRE: Carbapenem Resistant Enterobacteriaceae

Culture collection: Cultures of fully characterised organisms maintained in such a way as to minimise sub-culturing. See page 14.

ESBL: Extended Spectrum Beta-Lactamase-producing organism.

EUCAST: European Committee on Antimicrobial Susceptibility Testing.

First generation derivative: A single passage from a master culture, for example a Selectrol® disc.

Master culture: Culture derived from a reference culture vial.

NCPF®: National Collection of Pathogenic Fungi. NCPF® is a registered trademark of Public Health England.

NCTC®: National Collection of Type Cultures. NCTC® is a registered trademark of Public Health England.

Passage: An equivalent term for a subculture.

PHE: Public Health England.

Reference cultures: Quality control strains selected on the basis of their phenotypic biochemical and antimicrobial susceptibility characteristics to be used as controls in microbiological testing. These are obtained as freeze-dried vials from culture collections.

Stock culture: Cultures derived from a Selectrol® disc, which can be stored for up to a week, usually on agar slants.

Working cultures: Stock cultures further sub-cultured to provide 18-24 hour growth for use in testing.

WDCM: World Data Centre for Microorganisms

WFCC: World Federation for Culture Collections

SIGNIFICANT PROPERTIES AND USES OF SELECTROL® ORGANISMS

Aspergillus brasiliensis (formerly *Aspergillus niger*):

MM94 – NCPF® 2275 / ATCC® 16404 / WDCM 00053 – used in pharmaceutical industry for testing media and preservatives. Colonies are initially white or yellowish and on the reverse greyish or greenish-yellow. Sporing heads on the colony surface are initially pale, becoming dark brown to black. Sporulation may be inhibited in sealed plates.

Bacillus cereus:

MM21 – NCTC® 10320 / ATCC® 9634 / WDCM 00001 (recently renamed *Bacillus toyonensis*) – ISO 11133 recommended media and ID test control organism.

MM86 – NCTC® 7464 / ATCC® 10876 – **PHE** recommended media and ID test control organism.

Bacillus subtilis (*Bacillus subtilis* subsp. *spizizenii*):

MM29 – NCTC® 10400 / ATCC® 6633 / WDCM 00003 – used in antibiotic assays (fully sensitive), **PHE** recommended media and ID test control organism.



Bacteroides fragilis:

MM44 – NCTC® 9343 / ATCC® 25285 – type strain, **PHE** recommended strain for media and sensitivity test control.

Campylobacter jejuni (*Campylobacter jejuni* subsp. *jejuni*):

MM82 – NCTC® 11322 / ATCC® 29428 / WDCM 00156 – **PHE** recommended strain for media control.

MM36 – NCTC® 11351 / ATCC® 33560 – **EUCAST** recommended strain for susceptibility testing.

Candida albicans:

MM28 – NCPF® 3255 / ATCC® 2091 / WDCM 00055 – sensitivity control / industrial use.

MM42 – NCPF® 3179 / ATCC® 10231 / WDCM 00054 – pharmaceutical / media testing / **PHE** recommended strain for media control.

CRE ≡ 'Carbapenem Resistant Enterobacteriaceae' / CPE ≡ 'Carbapenemase Producing Enterobacteriaceae'

There are 5 carbapenemases which are currently a significant problem in the UK – KPC, OXA-48, IMP, NDM and VIM – and PHE recommend that all clinically-significant Gram-negative bacteria should be routinely screened for carbapenemase production, using a recommended carbapenem² such as ertapenem or meropenem. Resistant isolates may be investigated further to determine which resistance mechanism is involved using the Modified Hodge Test, MALDI-TOF, PCR or a reference laboratory.

MM55 *Klebsiella pneumoniae* – NCTC® 13440 – produces a Class B VIM-1 Carbapenemase.

MM56 *Klebsiella pneumoniae* – NCTC® 13443 – produces a Class B NDM-1 Carbapenemase.

MM58 *Klebsiella pneumoniae* – NCTC® 13438 – produces a Class A KPC-3 Carbapenemase.

MM59 *Klebsiella pneumoniae* – NCTC® 13442 – produces a Class D OXA-48 Carbapenemase.

MM57 *Escherichia coli* – NCTC® 13476 – produces a Class B IMP Carbapenemase.

MM33 *Escherichia coli* – NCTC® 10418 / ATCC® 10536 – recommended by **PHE** as a negative control for CRE testing.

Citrobacter freundii:

MM27 – NCTC® 9750 / ATCC® 8090 – type strain.

Clostridium perfringens:

MM45 – NCTC® 8237 / ATCC® 13124 / WDCM 00007 – type strain. **PHE** recommended strain for food testing (Tryptose Sulphite Cycloserine agar – lactose and gelatin positive) and sensitivity test control. *Clostridium perfringens* is listed in Schedule 5 of the Anti-terrorism, Crime and Security Act 2001, and should be securely stored in accordance with the guidelines of the Act. However, MM45 is a type A strain, which does not produce the lethal epsilon toxin of potential interest to bioterrorists.

Clostridium sporogenes:

MM31 – NCTC® 532 / ATCC® 19404 / WDCM 00008 – used for media control. **PHE** recommended strain for media QC (lactose gelatin medium for ID of *C. perfringens* lactose negative and gelatin positive).

Enterobacter aerogenes:

MM26 – NCTC® 10006 / ATCC® 13048 / WDCM 00175 – type strain; used in water, paint and adhesive testing.

Enterobacter cloacae:

MM01 – NCTC® 13380 / ATCC® 23355 / WDCM 00082 – disinfectant control, media testing.

MM51 – NCTC® 13406 – **PHE** recommended strain for QC of AmpC (de-repressed) detection.

Enterococcus faecalis:

MM52 – NCTC® 13379 / ATCC® 51299 / WDCM 00085 – is vancomycin resistant (low-level VanB mediated) and also shows high-level resistance to aminoglycosides. It is used to confirm methodologies used to detect these resistances are working correctly. Lancefield group D.

MM17 – NCTC® 775 / ATCC® 19433 / WDCM 00009 – used in water industry and QC. **PHE** recommended strain for media control. Fully sensitive. Lancefield group D.

MM18 – NCTC® 12697 / ATCC® 29212 / WDCM 00087 – is fully sensitive to vancomycin and gentamicin. **PHE** recommended positive control strain for aesculin test. **CLSI**, **EUCAST** recommended media control for sulpha / trimethoprim testing and general susceptibility testing control. Lancefield group D.

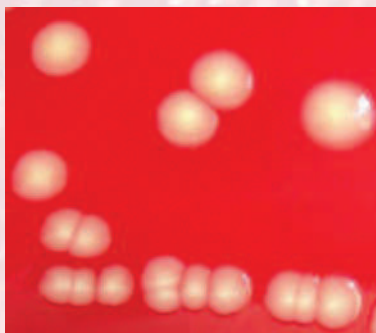


***Enterococcus hirae*:**

MM35 – NCTC® 13383 / ATCC® 10541 / WDCM 00011 – disinfectant control. Used in microbiological assays. Colonies are alpha-haemolytic on sheep blood agar.

***Escherichia coli* strains:**

MM02 – NCTC® 12241 / ATCC® 25922 / WDCM 00013 – **EUCAST**, **CLSI**, **PHE** recommended control strain for susceptibility testing (fully sensitive). Exhibits 2 colony types – the most prevalent type is slightly irregular, smooth and translucent. The secondary type appears more opaque. It is preferable to maintain cultures on agar as passage in broth can result in a change in MIC levels.



MM57 – NCTC® 13476 – CRE testing control; produces a Class B IMP Carbapenemase.

MM33 – NCTC® 10418 / ATCC® 10536 – (**PHE** recommended alternative to NCTC 12241) fully sensitive control strain. **PHE** recommended positive control for indole test, ONPG test, negative control for oxidase test, **PHE** recommended negative control for CRE and ESBL testing.

MM24 – NCTC® 11954 / ATCC® 35218 – beta-lactamase positive strain. **CLSI** recommended strain for susceptibility testing ONLY for penicillin / beta-lactamase inhibitor combinations. Sensitive to amoxicillin / clavulanic acid.

MM75 – NCTC® 9001 / ATCC® 11775 / WDCM 00090 – used in water / chemical industry. **PHE** recommended strain for media QC.

MM93 – NCTC® 12900 / ATCC® 700728 / WDCM 00014 – O157 strain (non-toxigenic). **PHE** recommended strain for media QC.

MM63 – NCTC® 11560 – beta-lactamase positive strain.

MM38 – NCTC® 12923 / ATCC® 8739 / WDCM 00012 – used in pharmaceutical / water industry. Three colony types: A) Entire, glistening, smooth and translucent. B) Entire, glistening smooth and opaque. C) Irregular, rough and translucent. The rough colonies appear after 48 hours incubation.

MM34 – NCTC® 13846 – Possesses the plasmid-mediated mcr-1 colistin resistance mechanism gene and is recommended by **PHE** and **EUCAST** as a control for tests to detect this increasingly prevalent resistance, in conjunction with NCTC® 12241 / ATCC® 25922 (Selectrol strain MM02) as a negative control.

***Haemophilus influenzae* strains:**

MM81 - NCTC® 12699 / ATCC® 49247 – is a 'BLNAR' strain – (beta-lactamase non-producing ampicillin / amoxycillin resistant). These strains are important clinically because the susceptibility results obtained using conventional testing procedures maybe misleading in the case cephalosporins. **PHE**, **CLSI** recommended QC strain for susceptibility testing media.

MM98 – NCTC® 11931 – a fully sensitive strain. **PHE** recommended strain for porphyrin synthesis test, chocolate agar control.

MM100 – NCTC® 8468 / ATCC® 9334 / CCUG 23946 – another fully sensitive strain, which reportedly gives results which are easier to interpret when Mueller-Hinton medium is used in preference to Iso-Sensitest medium. MIC for amoxycillin is 0.5 mg/l.

MM37 – NCTC® 12975 / ATCC® 49766 – recommended by **EUCAST**.

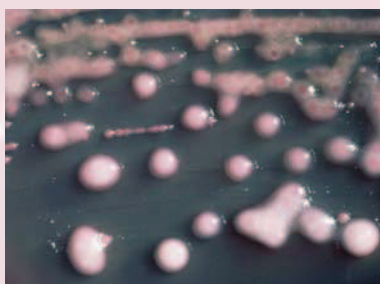


***Klebsiella* strains:**

MM04 *Klebsiella pneumoniae* – NCTC® 9633 / ATCC® 13883 / WDCM 00097 – type strain. Two colony types may be seen. The predominant type is entire and opaque. The secondary type is slightly smaller and translucent.

MM83 *Klebsiella pneumoniae* – NCTC® 13368 / ATCC® 700603 – ESBL-producing strain used as control for ESBL testing. There are two colony types.

MM55 *Klebsiella pneumoniae* – NCTC® 13440 – CRE testing control; produces a Class B VIM-1 Carbapenemase.



MM56 *Klebsiella pneumoniae* – NCTC® 13443 – CRE testing control; produces a Class B NDM-1 Carbapenemase.

MM58 *Klebsiella pneumoniae* – NCTC® 13438 – CRE testing control; produces a Class A KPC-3 Carbapenemase.

MM59 *Klebsiella pneumoniae* – NCTC® 13442 – CRE testing control; produces a Class D OXA-48 Carbapenemase.

MM88 *Klebsiella aerogenes* (*Raoultella planticola*) – NCTC® 9528 – used in water / pharmaceutical industry. **PHE** recommended negative control for Tryptone Bile X-Glucuronide agar and Yeast Extract agar.



Lactobacillus brevis:

MM76 – NCTC® 13386 / ATCC® 8287 – used in food industry.

***Legionella pneumophila* serogroup 1:**

MM08 – NCTC® 11192 / ATCC® 33152 / WDCM 00107 – derived from strain isolated from first recognised outbreak of legionellosis in Philadelphia at the Legionnaires' Convention 1976

Listeria innocua:

MM92 – NCTC® 11288 / ATCC® 33090 / WDCM 00017 – type strain. Non-pathogenic.

Listeria monocytogenes:

MM87 – NCTC® 11994 / WDCM 00019 – type strain, **PHE** recommended positive control strain for *Listeria* detection in food. Serotype 4b, most common serovar isolated from human infections.

MM48 – NCTC® 7973 / ATCC® 35152 / WDCM 00109 – produces 2 phenotypes, one is beta-haemolytic and virulent, the other non-haemolytic and non-virulent. Serovar 1/2a.

MM77 – NCTC® 13372 / ATCC® 7644 – used in food microbiology Q.C. Colonies exhibit beta-haemolysis on sheep blood agar.

Neisseria gonorrhoeae:

MM96 – NCTC® 12700 / ATCC® 49226 – has low-level, but clinically relevant, resistance to penicillin – MIC of penicillin is 0.5 mg/l. **PHE** recommended control for susceptibility testing – methodology assesses the ability of testing to detect resistance rather than sensitivity; this strain has low-level, but clinically relevant, resistance to penicillin – MIC of penicillin is 0.5 mg/l. Some variation in size and texture of colonies may be observed. Increased CO₂ is helpful in growth.

MM05 – NCTC® 8375 / ATCC® 19424 – is fully sensitive – MIC of penicillin is 0.06 mg/l. **PHE** recommended strain for media QC.

Proteus mirabilis:

MM43 – NCTC® 13376 / ATCC® 14153 – pharmaceutical / disinfectant / media control.

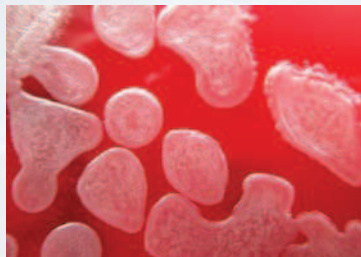
MM68 – NCTC® 10975 – media control. **PHE** recommended control for motility test.

Proteus vulgaris:

MM09 – NCTC® 4175 / ATCC® 13315 – was the type strain, but is atypical and has been recognised as a separate species – *Proteus hauseri* – it is used for media control. Colonies are glistening with spreading edges.

***Pseudomonas aeruginosa* strains:**

MM10 – NCTC® 12903 / ATCC® 27853 / WDCM 00025 – is fully sensitive to anti-pseudomonal antibiotics (EUCAST susceptibility test control). 2 colony types may be observed: A) predominantly flat, spreading edges and rough surface; B) small and compact. Produces both fluorescein and pyocyanin pigments.



MM65 – NCTC® 10662 / ATCC® 25668 / WDCM 00114 – is fully sensitive. PHE recommended control strain for media control

MM40 – NCTC® 12924 / ATCC® 9027 / WDCM 00026 – used in water industry / disinfectant testing. Colonies on agar plates are entire, glistening and mucoid with a grainy surface. This strain also produces both fluorescein and pyocyanin pigments.

MM41 – NCTC® 13359 / ATCC® 15442 – used in water industry / disinfectant testing. May produce up to 3 different colony types. Pyocyanin is not produced.

Rhodococcus equi:

MM97 – NCTC® 1621 / ATCC® 6939 / WDCM 00028 – type strain.

Saccharomyces cerevisiae:

MM73 – NCPF® 3178 – PHE recommended strain for food testing and enumeration of yeasts and moulds.

MM50 — NCTC® 10716 / WDCM 00058 – used for QC of culture media and for antifungal susceptibility testing.

***Salmonella* serotypes:**

MM11 *Salmonella* Typhimurium – NCTC® 12023 / ATCC® 14028 / WDCM 00031 – (1,4,5,12: i: 1,2) Used for media/test QC. This is a common serotype from animals and from human infections.

The strains listed below are unusual serotypes, used to avoid any chance of confusion with strains commonly found in animals, food, etc, and are used to control media and detection methods in the food industry:

MM89 *Salmonella* Poona – NCTC® 4840 – (13,22: z: 1,6) PHE recommended control strain for food testing.

MM84 *Salmonella* Nottingham – NCTC® 7832 – (16: d: e,n,z15) PHE recommended control for water testing.

Serratia marcescens:

MM12 – NCTC® 13382 / ATCC® 8100 – used for disinfectant testing. PHE recommended negative control for indole test. Colonies are entire, glistening, smooth and translucent. Non-pigmented.

Staphylococcus aureus:

(A) Fully sensitive:

MM85 – NCTC® 6571 / ATCC® 9144 / WDCM 00035 – historically used for susceptibility testing ('Oxford staph'), but largely superseded by MM13 as it has unusually low MIC's and so is unrepresentative of normal range of *Staph aureus* strains. Sensitive to penicillin and ceftazidime / methicillin / oxacillin. **PHE** recommended coagulase, DNase and catalase positive control.

MM13 – NCTC® 12981 / ATCC® 25923 / WDCM 00034 – used in susceptibility and media testing/QC. Fully sensitive to all anti-staphylococcal antibiotics (including penicillin and methicillin / oxacillin). It is preferable to maintain cultures on agar as passage in broth can result in a change in MIC levels. Colonies are circular white to cream, convex to flat in elevation. After 48 hours incubation a few grey/translucent variants may be noted. Beta-haemolytic on sheep blood agar.

B) Penicillin resistant:

MM14 – NCTC® 12973 / ATCC® 29213 / WDCM 00131 – used for susceptibility testing, especially for automated methodology. **EUCAST**, **CLSI** strain. Sensitive to ceftazidime / methicillin / oxacillin. Penicillin resistant – weak beta-lactamase producer. Colonies are beta-haemolytic, and a golden-orange colour.

MM30 – NCTC® 7447 / ATCC® 6538P / WDCM 00033 – used for susceptibility testing/antibiotic assay, disinfectant testing. Ceftazidime / methicillin / oxacillin sensitive. Penicillin resistant. Colonies are weakly beta-haemolytic, coagulase positive and beta-lactamase negative.

(C) MRSA (ceftazidime / methicillin / oxacillin resistant):

MM91 – NCTC® 13373 / ATCC® 43300 / WDCM 00211 (MRSA) – Possesses *mecA* gene but is hetero-resistant, (so as few as one per thousand cells demonstrate the resistance) and consequently has low-level ceftazidime / oxacillin / methicillin resistance (4.0 mg/l MIC of oxacillin, 8.0 mg/l MIC of ceftazidime – methicillin sensitive strains have MIC of 0.12-0.5 for oxacillin and 1-4 for ceftazidime.); it is used to confirm testing procedures for methicillin resistance are working and provides a more stringent test than testing with an MRSA which shows homogeneous resistance and has a much higher MIC. This organism will have a zone of inhibition reduced in size compared to a fully ceftazidime / oxacillin / methicillin sensitive strain (such as MM13). **CLSI** recommended strain for MRSA testing. There are two colony types: 1) Beta-haemolytic with a slight yellow tint. 2) Non-haemolytic and white.

MM64 – NCTC® 12493 / WDCM 00212 (MRSA) – possesses *mecA* gene and shows homogeneous resistance with MIC of >64 for methicillin, which produces high-level ceftazidime / methicillin / oxacillin resistance. **EUCAST** recommended strain. Instances have been reported where loss of the *mecA* gene has occurred during storage.

D) Other:

MM46 – NCTC® 10788 / ATCC® 6538 / WDCM 00032 – used in pharmaceutical industry for testing disinfectants etc. Usually yellow pigmented colonies, or can produce a white colonial variant. Beta-haemolytic.



Staphylococcus epidermidis:

MM15 – NCTC® 13360 / ATCC® 12228 / WDCM 00036 – used for media control / antibiotic assay. Colonies are small and beta-haemolytic.

Streptococcus agalactiae: (Beta-haemolytic Streptococcus group B)

MM16 – NCTC® 8181 / ATCC® 13813 – type strain, used for QC. **PHE** recommended negative control for aesculin test.

***Streptococcus pneumoniae* strains:**

MM95 – NCTC® 12977 / ATCC® 49619 – has low-level, but clinically relevant, resistance to penicillin – this organism is used to assess detection of resistance rather than sensitivity. **PHE** recommended positive control for bile solubility test. **CLSI, EUCAST** recommended control strain for susceptibility testing. Serotype 19F.

MM19 – NCTC® 12695 / ATCC® 6303 – is fully sensitive. Colonies are mucoid and alpha-haemolytic. A few colonies may have an irregular edge. Serotype 3.



Streptococcus pyogenes:

MM20 – NCTC® 12696 / ATCC® 19615 – used for QC and media testing. Lancefield group A, beta-haemolytic. **PHE** recommended blood agar control.

Vibrio parahaemolyticus:

MM06 – NCTC® 10885 / WDCM 00185 – used for QC of media and ID testing. **PHE** recommended strain used mainly in the food industry.

Yersinia enterocolitica:

MM80 – NCTC® 12982 / ATCC® 9610 / WDCM 00038 – type strain, used for media control. Serotype O:8, which is a pathogenic serotype, commonest in USA.

References:

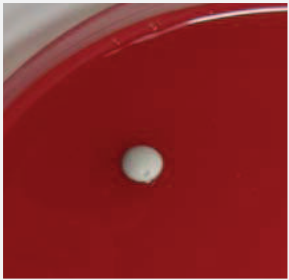
- 1 European Committee on Antimicrobial Susceptibility Testing (EUCAST). Routine and Extended Internal Quality Control for MIC Determination and Disc Diffusion. Version 7.0 - 01.01.2017.
- 2 UK Standards for Microbiology Investigations. Example Reference Strains for Microbiology Investigations Test Procedures: Bacteriology—Test Procedures | TP 1 | Issue No. 2 | 05.01.2015. Public Health England (PHE).
- 3 Performance Standards for Antimicrobial Disc Susceptibility Tests: Approved Standard—11th Edition. Clinical and Laboratory Standards Institute (CLSI).

How to use Selectrol®

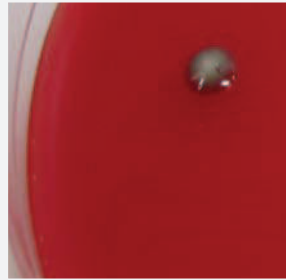
Always warm the vial to ambient temperature before opening.

Be sure to use non-selective culture media to revive the organisms.

For the more fastidious organisms, such as anaerobes, it is generally better to use agar rather than broth for revival.



Place disc on suitable growth medium such as blood agar



Leave disc for a few minutes to liquefy, then spread plate and incubate to produce isolated colonies



Place disc in a small volume of a suitable broth medium such as brain-heart infusion



Allow disc a few minutes to dissolve, then spread aliquot onto a plate of suitable growth medium



Obtain a stock culture which can be used to prepare an inoculum for biochemical and antibiotic susceptibility tests

Out-of-specification results

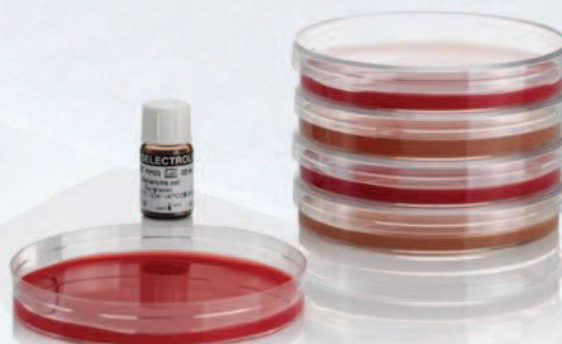
Laboratories use Selectrol® for Quality Control of culture media, biochemical identification tests and antimicrobial susceptibility testing. When a laboratory test result, an MIC or biochemical reaction, is unexpected or out-of-specification, the test should first be repeated to confirm it; an out-of-specification result is an indication that the testing procedure should be reviewed; it is not, in the first instance, a sign of a problem with the control organism.

If incorrect results are obtained on retesting, the explanation could be:

- The test procedure was not followed correctly – check standard operating procedures
- There is an instrumentation error – check calibration, mechanical functioning, etc
- There is a problem with the consumables – out of date, incorrect storage, etc
- The culture of the control organism has become contaminated

Technical Support

If no explanation for out-of-spec results can be found, but repeated tests still give unacceptable results, please contact TCS and / or your relevant reference laboratory or instrument manufacturer for advice. For example, contact AMRHAI at Colindale, London if MIC results are consistently outside the acceptable range. Please retain any remaining discs of organisms about which you have concerns so they can be returned to TCS and investigated alongside retained samples.



Preparing QC and Validation Spikes from Selectrol®

Preparing the spike

- Place a Selectrol® disc in Brain Heart Infusion (BHI) broth* or equivalent, and culture (typically for 18 hours) at the appropriate temperature for the organism (typically 37°C)
- Assume the count in the broth to be 10^8 organisms per ml ----- (A)
- Mix and transfer 100 µl of (A) to 100 ml of saline or ¼ strength Ringer's solution -- (B)
- Mix and transfer 100 µl of (B) to 10 ml of saline or ¼ strength Ringer's solution --- (C)
- Mix and transfer 100 µl of (C) to your homogenised food sample.

Verifying the inoculum

- Pipette 5 x 10 µl drops from (C) onto each of two agar plates for Miles and Misra counts.

Using the assumptions and dilutions above:

- (A) contains 10^8 organisms per ml
- (B) contains 10^5 organisms per ml
- (C) contains 10^3 organisms per ml

If the Miles and Misra counts indicate that the required count was not achieved:

- If the count was too high by a factor of 10, reduce the volume transferred from (A) to (B) from 100 µl to 10 µl
- If the count was too low by a factor of 10, increase the volume transferred from (A) to (B) from 100 µl to 1 ml.

Keep a record of the correct dilutions for each organism type for future use. You will find that this method is very repeatable.

*Note: BHI broth will work for most of the Selectrol® organisms; however, for fastidious organisms an appropriate culture broth must be selected, e.g. Fastidious Anaerobe Broth for strictly anaerobic organisms.





Culture Collections

Cultures of microorganisms have been deposited and subsequently maintained in 589 collections in 68 countries, and many of the cultures are derived from the same original isolate; the history of each organism, its properties and names of the culture collections which hold it are detailed in the relevant catalogues and websites.

Some of the organisms have been selected and recommended by expert organisations to be supplied as controls for microbiological tests, and when the identical cultures are present in more than one collection they will have a specific designation for each, incorporating the abbreviation for the collection and a reference number.

For example:- *Staphylococcus aureus* NCTC 7447, widely recommended as a control for antimicrobial susceptibility testing, is held in 30 collections, and consequently the phenotypically and genotypically identical organism has 30 different references, such as ATCC 6538P, CIP 53.156, DSM 346 and so on.

In an effort to minimise potential confusion and help users find local sources of reference strains, the WFCC and the WDCM initiated a system that ascribes each recommended QC strain a reference number (WDCM 00001 onwards), cites all collections that contain it and provides contact details and each collection's unique reference. For example, the strain of *Staphylococcus aureus* NCTC 7447 (Selectrol® strain MM33) mentioned above is designated WDCM 00033.

***Staphylococcus aureus* WDCM 00033**

AHU 1142; **ATCC™ 6538P**; BCRC 10451 ; BTCC 209P; BU 395; CCM 2022; CCTM 596; CCUG 1828; CECT 240; CIP 53.156; CN 3784; CNCTC Mau 28/58; DSM 346; FIRDI 451; IAM 1011; IAM 12082; IEM Mau 28/58; IFO 12732; IFO 3061; IID 671; IMET 10904; JCM 2151; LMG 8195; NCIMB 8625; **NCTC 7447**; NRRL B-313; OUT 8232; PCI 1209; PZH 8/54; RIMD 3109007; VNIIA 209P;

Products derived from the cultures in the collections should be manufactured using the minimum number of sub-cultures, to minimise the possibility of alterations to the phenotype due to mutations. Ideally, as in the case of **Selectrol®**, a single sub-culture only is used, so the **Selectrol®** product is a 'first generation derivative' of a culture supplied by NCTC, and will be identical with regard to its properties and suitability for use in QC applications to a culture of the particular organism obtained from any of the other WDCM listed culture collections.

Every effort has been made to ensure the accuracy of the information in this document, however TCS makes no warranties, expressed or implied, regarding errors or omissions and assumes no legal liability or responsibility for loss or damage resulting from the use of information contained within.

Selectrol Strain Index

Strain Name	Designation	Code	WDCM
<i>Aspergillus brasiliensis</i>	NCPF [®] 2275 / ATCC [®] 16404	MM94	00053
<i>Bacillus cereus</i>	NCTC [®] 10320 / ATCC [®] 9634	MM21	00001
<i>Bacillus cereus</i>	NCTC [®] 7464 / ATCC [®] 10876	MM86	
<i>Bacillus subtilis</i>	NCTC [®] 10400 / ATCC [®] 6633	MM29	00003
<i>Bacteroides fragilis</i>	NCTC [®] 9343 / ATCC [®] 25285	MM44	
<i>Campylobacter jejuni</i>	NCTC [®] 11351 / ATCC [®] 33560	MM36	
<i>Campylobacter jejuni</i>	NCTC [®] 11322 / ATCC [®] 29428	MM82	00156
<i>Candida albicans</i>	NCPF [®] 3255 / ATCC [®] 2091	MM28	00055
<i>Candida albicans</i>	NCPF [®] 3179 / ATCC [®] 10231	MM42	00054
<i>Citrobacter freundii</i>	NCTC [®] 9750 / ATCC [®] 8090	MM27	
<i>Clostridium perfringens</i>	NCTC [®] 8237 / ATCC [®] 13124	MM45	00007
<i>Clostridium sporogenes</i>	NCTC [®] 532 / ATCC [®] 19404	MM31	00008
<i>Enterobacter aerogenes</i>	NCTC [®] 10006 / ATCC [®] 13048	MM26	00175
<i>Enterobacter cloacae</i>	NCTC [®] 13380 / ATCC [®] 23355	MM01	00082
<i>Enterobacter cloacae</i>	NCTC [®] 13406	MM51	
<i>Enterococcus faecalis</i>	NCTC [®] 775 / ATCC [®] 19433	MM17	00009
<i>Enterococcus faecalis</i>	NCTC [®] 12697 / ATCC [®] 29212	MM18	00087
<i>Enterococcus faecalis</i>	NCTC [®] 13379 / ATCC [®] 51299	MM52	00085
<i>Enterococcus hirae</i>	NCTC [®] 13383 / ATCC [®] 10541	MM35	00011
<i>Escherichia coli</i>	NCTC [®] 12241 / ATCC [®] 25922	MM02	00013
<i>Escherichia coli</i>	NCTC [®] 11954 / ATCC [®] 35218	MM24	
<i>Escherichia coli</i>	NCTC [®] 10418 / ATCC [®] 10536	MM33	
<i>Escherichia coli</i>	NCTC [®] 12923 / ATCC [®] 8739	MM38	00012
<i>Escherichia coli</i>	NCTC [®] 11560	MM63	
<i>Escherichia coli</i>	NCTC [®] 9001 / ATCC [®] 11775	MM75	00090
<i>Escherichia coli</i> CRE	NCTC [®] 13476	MM57	
<i>Escherichia coli</i> (mcr-1)	NCTC [®] 13846	MM34	
<i>Escherichia coli</i> O157 (non-toxigenic)	NCTC [®] 12900 / ATCC [®] 700728	MM93	00014
<i>Haemophilus influenzae</i>	NCTC [®] 8468 / ATCC [®] 9334	MM100	
<i>Haemophilus influenzae</i>	NCTC [®] 12975 / ATCC [®] 49766	MM37	
<i>Haemophilus influenzae</i>	NCTC [®] 12699 / ATCC [®] 49247	MM81	
<i>Haemophilus influenzae</i>	NCTC [®] 11931	MM98	
<i>Klebsiella aerogenes</i>	NCTC [®] 9528	MM88	
<i>Klebsiella pneumoniae</i>	NCTC [®] 9633 / ATCC [®] 13883	MM04	00097
<i>Klebsiella pneumoniae</i>	NCTC [®] 13368 / ATCC [®] 700603	MM83	
<i>Klebsiella pneumoniae</i> CRE	NCTC [®] 13440	MM55	
<i>Klebsiella pneumoniae</i> CRE	NCTC [®] 13443	MM56	
<i>Klebsiella pneumoniae</i> CRE	NCTC [®] 13438	MM58	

Selectrol Strain Index

Strain Name	Designation	Code	WDCM
<i>Klebsiella pneumoniae</i> CRE	NCTC [®] 13442	MM59	
<i>Lactobacillus brevis</i>	NCTC [®] 13386 / ATCC [®] 8287	MM76	
<i>Legionella pneumophila</i> serogroup 1	NCTC [®] 11192 / ATCC [®] 33152	MM08	00107
<i>Listeria innocua</i>	NCTC [®] 11288 / ATCC [®] 33090	MM92	00017
<i>Listeria monocytogenes</i>	NCTC [®] 7973 / ATCC [®] 35152	MM48	00109
<i>Listeria monocytogenes</i>	NCTC [®] 13372 ATCC [®] 7644	MM77	
<i>Listeria monocytogenes</i>	NCTC [®] 11994	MM87	00019
<i>Neisseria gonorrhoeae</i>	NCTC [®] 8375 / ATCC [®] 19424	MM05	
<i>Neisseria gonorrhoeae</i>	NCTC [®] 12700 / ATCC [®] 49226	MM96	
<i>Proteus mirabilis</i>	NCTC [®] 13376 / ATCC [®] 14153	MM43	
<i>Proteus mirabilis</i>	NCTC [®] 10975	MM68	
<i>Proteus vulgaris</i>	NCTC [®] 4175 / ATCC [®] 13315	MM09	
<i>Pseudomonas aeruginosa</i>	NCTC [®] 12903 / ATCC [®] 27853	MM10	00025
<i>Pseudomonas aeruginosa</i>	NCTC [®] 12924 / ATCC [®] 9027	MM40	00026
<i>Pseudomonas aeruginosa</i>	NCTC [®] 13359 / ATCC [®] 15442	MM41	
<i>Pseudomonas aeruginosa</i>	NCTC [®] 10662 / ATCC [®] 25668	MM65	00114
<i>Rhodococcus equi</i>	NCTC [®] 1621 / ATCC [®] 6939	MM97	00028
<i>Saccharomyces cerevisiae</i>	NCTC [®] 10716/ ATCC [®] 9763	MM50	00058
<i>Saccharomyces cerevisiae</i>	NCPF [®] 3178	MM73	
<i>Salmonella</i> Nottingham	NCTC [®] 7832	MM84	
<i>Salmonella</i> Poona	NCTC [®] 4840	MM89	
<i>Salmonella</i> Typhimurium	NCTC [®] 12023/ ATCC [®] 14028	MM11	00031
<i>Serratia marcescens</i>	NCTC [®] 13382 / ATCC [®] 8100	MM12	
<i>Staphylococcus aureus</i>	NCTC [®] 12981 / ATCC [®] 25923	MM13	00034
<i>Staphylococcus aureus</i>	NCTC [®] 12973 / ATCC [®] 29213	MM14	00131
<i>Staphylococcus aureus</i>	NCTC [®] 7447 / ATCC [®] 6538P	MM30	00033
<i>Staphylococcus aureus</i>	NCTC [®] 10788 / ATCC [®] 6538	MM46	00032
<i>Staphylococcus aureus</i>	NCTC [®] 6571 / ATCC [®] 9144	MM85	00035
<i>Staphylococcus aureus</i> (MRSA)	NCTC [®] 12493	MM64	00212
<i>Staphylococcus aureus</i> (MRSA)	NCTC [®] 13373 / ATCC [®] 43300	MM91	00211
<i>Staphylococcus epidermidis</i>	NCTC [®] 13360 / ATCC [®] 12228	MM15	00036
<i>Streptococcus agalactiae</i>	NCTC [®] 8181 / ATCC [®] 13813	MM16	
<i>Streptococcus pneumoniae</i>	NCTC [®] 12695 / ATCC [®] 6303	MM19	
<i>Streptococcus pneumoniae</i>	NCTC [®] 12977 / ATCC [®] 49619	MM95	
<i>Streptococcus pyogenes</i>	NCTC [®] 12696 / ATCC [®] 19615	MM20	
<i>Vibrio parahaemolyticus</i>	NCTC [®] 10885	MM06	00185
<i>Yersinia enterocolitica</i>	NCTC [®] 12982 / ATCC [®] 9610	MM80	00038

Selectrol Strains Listed by WDCM Number

WDCM	Strain Name	Designation	Code
00001	<i>Bacillus cereus</i>	NCTC [®] 10320 / ATCC [®] 9634	MM21
00003	<i>Bacillus subtilis</i>	NCTC [®] 10400 / ATCC [®] 6633	MM29
00007	<i>Clostridium perfringens</i>	NCTC [®] 8237 / ATCC [®] 13124	MM45
00008	<i>Clostridium sporogenes</i>	NCTC [®] 532 / ATCC [®] 19404	MM31
00009	<i>Enterococcus faecalis</i>	NCTC [®] 775 / ATCC [®] 19433	MM17
00011	<i>Enterococcus hirae</i>	NCTC [®] 13383 / ATCC [®] 10541	MM35
00012	<i>Escherichia coli</i>	NCTC [®] 12923 / ATCC [®] 8739	MM38
00013	<i>Escherichia coli</i>	NCTC [®] 12241 / ATCC [®] 25922	MM02
00014	<i>Escherichia coli</i> O157 (non-toxigenic)	NCTC [®] 12900 / ATCC [®] 700728	MM93
00017	<i>Listeria innocua</i>	NCTC [®] 11288 / ATCC [®] 33090	MM92
00019	<i>Listeria monocytogenes</i>	NCTC [®] 11994	MM87
00025	<i>Pseudomonas aeruginosa</i>	NCTC [®] 12903 / ATCC [®] 27853	MM10
00026	<i>Pseudomonas aeruginosa</i>	NCTC [®] 12924 / ATCC [®] 9027	MM40
00028	<i>Rhodococcus equi</i>	NCTC [®] 1621 / ATCC [®] 6939	MM97
00031	<i>Salmonella</i> Typhimurium	NCTC [®] 12023 / ATCC [®] 14028	MM11
00032	<i>Staphylococcus aureus</i>	NCTC [®] 10788 / ATCC [®] 6538	MM46
00033	<i>Staphylococcus aureus</i>	NCTC [®] 7447 / ATCC [®] 6538P	MM30
00034	<i>Staphylococcus aureus</i>	NCTC [®] 12981 / ATCC [®] 25923	MM13
00035	<i>Staphylococcus aureus</i>	NCTC [®] 6571 / ATCC [®] 9144	MM85
00036	<i>Staphylococcus epidermidis</i>	NCTC [®] 13360 / ATCC [®] 12228	MM15
00038	<i>Yersinia enterocolitica</i>	NCTC [®] 12982 / ATCC [®] 9610	MM80
00053	<i>Aspergillus brasiliensis</i>	NCPF [®] 2275 / ATCC [®] 16404	MM94
00054	<i>Candida albicans</i>	NCPF [®] 3179 / ATCC [®] 10231	MM42
00055	<i>Candida albicans</i>	NCPF [®] 3255 / ATCC [®] 2091	MM28
00058	<i>Saccharomyces cerevisiae</i>	NCTC [®] 10716 / ATCC [®] 9763	MM50
00082	<i>Enterobacter cloacae</i>	NCTC [®] 13380 / ATCC [®] 23355	MM01
00085	<i>Enterococcus faecalis</i>	NCTC [®] 13379 / ATCC [®] 51299	MM52
00087	<i>Enterococcus faecalis</i>	NCTC [®] 12697 / ATCC [®] 29212	MM18
00090	<i>Escherichia coli</i>	NCTC [®] 9001 / ATCC [®] 11775	MM75
00097	<i>Klebsiella pneumoniae</i>	NCTC [®] 9633 / ATCC [®] 13883	MM04
00107	<i>Legionella pneumophila</i> serogroup 1	NCTC [®] 11192 / ATCC [®] 33152	MM08
00109	<i>Listeria monocytogenes</i>	NCTC [®] 7973 / ATCC [®] 35152	MM48
00114	<i>Pseudomonas aeruginosa</i>	NCTC [®] 10662 / ATCC [®] 25668	MM65
00131	<i>Staphylococcus aureus</i>	NCTC [®] 12973 / ATCC [®] 29213	MM14
00156	<i>Campylobacter jejuni</i>	NCTC [®] 11322 / ATCC [®] 29428	MM82
00175	<i>Enterobacter aerogenes</i>	NCTC [®] 10006 / ATCC [®] 13048	MM26
00185	<i>Vibrio parahaemolyticus</i>	NCTC [®] 10885	MM06
00211	<i>Staphylococcus aureus</i> (MRSA)	NCTC [®] 13373 / ATCC [®] 43300	MM91
00212	<i>Staphylococcus aureus</i> (MRSA)	NCTC [®] 12493	MM64

Notes





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